DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

GE Healthcare Coils (USA Instruments, Inc.)
% Ms. Candice Mandera
Regulatory Affairs Leader, Magnetic Resonance
1515 Danner Drive
AURORA OH 44202

March 6, 2015

Re: K143389
Trade/Device Name: 3.0T GEM RT Open Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: MOS
Dated: February 5, 2015
Received: February 6, 2015

Dear Ms. Mandera:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143389

Device Name
3.0T GEM RT Open Array

Indications for Use *(Describe)*
The 3.0T GEM RT Open Array Coil, part of the Oncology Suite, is a receive-only RF coil designed for use with 3.0T MRI systems manufactured by GE. The indications for use include the head, neck, and brachial plexus anatomies and vasculature imaging. The nucleus excited is hydrogen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 24, 2014
Submitter:	GE Healthcare Coils, (USA Instruments, Inc.) Establishment Registration Number: 1529041 1515 Danner Dr. Aurora, OH 44202-9273 USA
Primary Contact Person:	Candice Mandera Regulatory Affairs Leader GE Healthcare (USA Instruments, Inc.) 1515 Danner Drive Aurora, OH – 44202 USA Phone: 330-995-5708 Fax: 330-470-2661
Secondary Contact Person:	Andrew Menden Regulatory Affairs Manager GE Healthcare (GE Medical Systems LLC.) 3200 N Grandview Blvd., Mail Code – W-827 Waukesha, WI – 53188 USA Phone: 262-521-6223 Fax: 414-908-9585
Device: Trade Name:	3.0T GEM RT Open Array
Common/Usual Name:	Coil, Magnetic Resonance, Specialty
Classification Names:	21CFR 892.1000 – Magnetic resonance diagnostic device
Product Code:	MOS
Predicate Device(s):	K123327, 1.5T GEM RT Open Array
Device Description:	The 3.0T GEM RT Open Array is a receive-only coil designed to provide optimal penetration, uniformity, and signal to noise ratio for the posterior head-neck and brachial plexus. The 3.0T GEM RT Open Array coil is an 8-Channel Phased Array, which is sold as an

option to the Oncology Suite that is compatible with the 3.0T GE GEM compatible MR Scanner. The GEM RT Open Array is a posterior coil that comes with a P-connector that can be plugged into the head end (P2) or foot end (P4) of the 3.0T GEM patient table (K103327). When used with the Oncology suite the GEM RT Open Array coil can be inserted into the GEM cradle at the head end.

Intended Use:

The 3.0T GEM RT Open Array Coil, part of the Oncology Suite, is a receive-only RF coil designed for use with 3.0T MRI systems manufactured by GE. The indications for use include the head, neck, and brachial plexus anatomies and vasculature imaging. The nucleus excited is hydrogen.

Technology:

The GE 3.0T GEM RT Open Array is a multi-element phased array receive-only RF coil with integrated preamplifiers. The 3.0T GEM RT Open Array coil operates on the same principles and is an addition to the GEM suite of coils (K103327). The GEM RT Open Array is designed to fit into the GEM table at the head or foot end adjacent to where the existing integrated posterior array in the GEM table resides. The 3.0T GEM RT Open Array employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The GE 3.0T GEM RT Open Array has used the same non-clinical voluntary standards to demonstrate substantial equivalence of safety and performance:

AAMI/ANSI ES60601-1 (IEC 60601-1): Electrical Safety – compliant with all applicable sections

IEC 60601-1-2: Electromagnetic Compatibility – compliant with all applicable sections (i.e., electrostatic discharge)

IEC 60601-2-33: Electrical Safety – compliant with all

applicable sections

NEMA MS 6-2008: SNR and Uniformity of Phased Array Coils – compliant with all applicable sections.

The following quality assurance measures were applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, 3.0T GEM RT Open Array, did not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission.

Substantial Equivalence Conclusion:

The indications for use of the proposed device are identical to the claimed predicate device. The 3.0T GEM RT Open Array employs equivalent technology to the claimed predicate device. Additionally, the results from the above non-clinical tests demonstrate that the device performs as intended. Thus, the 3.0T GEM RT Open Array is substantially equivalent to the predicate device to which it has been compared.

Conclusion: GE Healthcare considers the 3.0T GEM RT Open Array to be as safe, as effective, and performance is substantially equivalent to the predicate device.